4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-5020]

Notice to Public of Website Location of the Office of the Chief Scientist Proposed Guidance Development List

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the website location where the Agency will post a list of possible topics for future guidance document development or revision by the Office of the Chief Scientist (OCS) during the next year. In addition, FDA has established a docket where interested persons may provide comments that could benefit the OCS guidance program and its engagement with stakeholders, including comments on the priority of topics for guidance. This feedback is critical to the OCS guidance program as we consider feedback from stakeholders along with Agency resources and priorities.

ADDRESSES: You may submit either electronic or written comments at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in

the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-5020 for "Notice to Public of Website Location of OCS Proposed Guidance Development Agenda." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out,

will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Jennifer Ross, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 301-796-4880 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

FDA welcomes comments on any or all of the topics for guidance documents on the list as explained in § 10.115(f)(5) (21 CFR 10.115(f)(5)). FDA has established Docket No. FDA-2023-N-5020 where comments on the list, drafts of proposed guidance documents on those or other topics, suggestions for new or different guidances within OCS's purview, and relative priority of listed guidance documents may be submitted and shared with the public (see ADDRESSES). FDA believes this docket is a valuable tool for receiving information from interested persons. FDA anticipates that feedback from interested persons will allow OCS to

better prioritize and more efficiently draft guidances to meet the needs of the Agency and our stakeholders.

Consistent with the Good Guidance Practices regulation at § 10.115(f)(4), OCS would appreciate suggestions that OCS revise or withdraw an already existing guidance document within OCS's purview. We request that the suggestion clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised.

II. Website Location of Guidance List

This notice announces the website location of the document that provides the list of possible topics for future guidance document development or revision by OCS during the next year. The initial list covers calendar year (CY) 2024. To access the list, visit FDA's website at https://www.fda.gov/about-fda/guidance-documents-office-chief-scientist/office-chief-scientist-guidance-documents-under-development. We note that the topics on this list may be removed or modified based on current priorities, as well as comments received regarding this list. Furthermore, several factors may impact FDA's ability to issue a guidance, including, for example, new Administration priorities, emerging public health issues, or other extenuating circumstances. The Agency is not required to publish every guidance on the list if, for example, the resources needed would be to the detriment of meeting other Agency priorities and statutory obligations. In addition, the Agency is not precluded from issuing guidance documents that are not on the list.

Dated: December 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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